



UNITED STATES PATENT AND TRADEMARK OFFICE

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Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

Steven P. O'Connor  
Finnegan Henderson Farabow Garrett & Dunner LLP  
901 New York Ave., NW  
Washington DC 20001-4413

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,868,112

Dear Mr. O'Connor :

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,868,112 for a period of 1,258 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: <http://www.fda.gov/opacom/morechoices/fdaforms/default.html> (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at [mary.till@uspto.gov](mailto:mary.till@uspto.gov).

Mary C. Till  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
HFD-7  
5600 Fishers Lane (Rockwall II Rm 1101)  
Rockville, MD 20857

RE: ReFacto® (novel procoagulant  
proteins)  
FDA Docket No.: 01E-0097

Attention: Beverly Friedman

# UNITED STATES PATENT AND TRADEMARK OFFICE

## (12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 4,868,112  
(45) ISSUED : September 19, 1989  
(75) INVENTOR : John J. Toole, Jr.  
(73) PATENT OWNER : Genetics Institute LLC  
(95) PRODUCT : ReFacto® (novel procoagulant proteins)

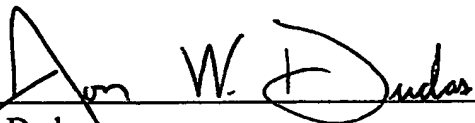
This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 4,868,112 based upon the regulatory review of the product ReFacto® (novel procoagulant proteins) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 1,258 days

from September 19, 2006, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 14th day of September 2006.

  
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Jon W. Dudas

Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office